**To:** CN=Alana Lee/OU=R9/O=USEPA/C=US@EPA;CN=Bella Dizon/OU=R9/O=USEPA/C=US@EPA;CN=Bonnie Arthur/OU=R9/O=USEPA/C=US@EPA;CN=Eric Yunker/OU=R9/O=USEPA/C=US@EPA;CN=Penny Reddy/OU=R9/O=USEPA/C=US@EPA;CN=Rachelle Thompson/OU=R9/O=USEPA/C=US@EPA;CN=Raymond Chavira/OU=R9/O=USEPA/C=US@EPA;CN=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]; N=Bella Dizon/OU=R9/O=USEPA/C=US@EPA;CN=Bonnie Arthur/OU=R9/O=USEPA/C=US@EPA;CN=Eric Yunker/OU=R9/O=USEPA/C=US@EPA;CN=Penny Reddy/OU=R9/O=USEPA/C=US@EPA;CN=Rachelle Thompson/OU=R9/O=USEPA/C=US@EPA;CN=Raymond Chavira/OU=R9/O=USEPA/C=US@EPA;CN=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]; N=Bonnie Arthur/OU=R9/O=USEPA/C=US@EPA;CN=Eric Yunker/OU=R9/O=USEPA/C=US@EPA;CN=Penny Reddy/OU=R9/O=USEPA/C=US@EPA;CN=Rachelle Thompson/OU=R9/O=USEPA/C=US@EPA;CN=Raymond Chavira/OU=R9/O=USEPA/C=US@EPA;CN=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]; N=Eric Yunker/OU=R9/O=USEPA/C=US@EPA;CN=Penny Reddy/OU=R9/O=USEPA/C=US@EPA;CN=Rachelle Thompson/OU=R9/O=USEPA/C=US@EPA;CN=Raymond Chavira/OU=R9/O=USEPA/C=US@EPA;CN=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]; N=Penny Reddy/OU=R9/O=USEPA/C=US@EPA;CN=Rachelle Thompson/OU=R9/O=USEPA/C=US@EPA;CN=Raymond Chavira/OU=R9/O=USEPA/C=US@EPA;CN=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]; N=Rachelle Thompson/OU=R9/O=USEPA/C=US@EPA;CN=Raymond Chavira/OU=R9/O=USEPA/C=US@EPA;CN=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]; N=Raymond Chavira/OU=R9/O=USEPA/C=US@EPA;CN=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]; N=Wayne Praskins/OU=R9/O=USEPA/C=US@EPA[]
**Cc:** []
**Bcc:** []
**From:** CN=Kelly Manheimer/OU=R9/O=USEPA/C=US
**Sent:** Mon 8/20/2012 5:01:12 PM
**Subject:** Fw: Inside EPA - Risk Group Agrees To Industry Request To Review EPA's New TCE Policies - Aug 17, 2012
TCEinsideepa2012_1559.pdf
2407698

Hi, team:
Interesting update on the TCE tox value issue - thanks to Alana for flagging it!

Regards,
Kelly Manheimer, Chief
CA Sites Cleanup Section III
EPA, Superfund, SFD7-3
direct: 415-972-3290
cell: 415-265-1168
----- Forwarded by Kelly Manheimer/R9/USEPA/US on 08/20/2012 10:00 AM -----

From: Alana Lee/R9/USEPA/US
To: Jane Diamond/R9/USEPA/US@EPA, Kathleen Salyer/R9/USEPA/US@EPA, Kelly Manheimer/R9/USEPA/US@EPA, Frederick Schauffler/R9/USEPA/US@EPA, John Chesnutt/R9/USEPA/US@EPA, Claire Trombadore/R9/USEPA/US@EPA, Gerald Hiatt/R9/USEPA/US@EPA, Daniel Stralka/R9/USEPA/US@EPA, Sophia Serda/R9/USEPA/US@EPA, Harold Ball/R9/USEPA/US@EPA, Stan Smucker/R9/USEPA/US@EPA, Bethany Dreyfus/R9/USEPA/US@EPA, Michael Gill/R9/USEPA/US@EPA, Rusty Harris-Bishop/R9/USEPA/US@EPA,
Date: 08/20/2012 05:50 AM
Subject: Inside EPA - Risk Group Agrees To Industry Request To Review EPA's New TCE Policies - Aug 17, 2012

Superfund Report - 08/20/2012
Risk Group Agrees To Industry Request To Review EPA's New TCE Policies
Posted: August 17, 2012
An alliance of risk assessment experts has agreed to a request from a group concerned about costly cleanups to convene a panel of experts to review EPA policy decisions regarding the ubiquitous solvent trichloroethylene (TCE) -- an area of growing concern since the agency strengthened its risk values for the contaminant last year.
The Alliance for Risk Assessment (ARA), a group of environmental consultants and other risk experts that crafts technical risk assessment products and services, Aug. 15 agreed to a request from the Alliance for Site Closure (ASC), which advises cleanup professionals, property owners and insurance companies on strategies to assess and resolve issues stemming from contamination, to convene a panel to address several concerns related to EPA's risk assessment of TCE, as well as early agency efforts to apply the new risk values at waste sites. The request is available at InsideEPA.com. (Doc ID: 2407698) [Attached as pdf in case unable to access]
A source with ARA says the panel will include high-level scientists from industry, government and academia to review "questionable areas around TCE," and consider how recent policy choices regarding TCE will affect site assessments. ARA's steering committee includes representatives from Texas, Indiana and Oregon state government as well as EPA.
The panel's review will likely last for months and will result in a report and possibly guidance, according to officials with ARA. The site closure group sought the alliance's assistance to assemble a broader team of experts then ASC could.
Of particular concern for the site closure group are the non-cancer risk values EPA set in its recently finalized Integrated Risk Information System (IRIS) assessment for TCE, as well as its decision to list cardiac birth defects as a potential adverse endpoint from TCE exposure.
In its IRIS assessment, EPA set a reference concentration (RfC) -- or the amount of the substance EPA anticipates can be inhaled daily over a lifetime without causing adverse health effects -- of 2 micrograms per cubic meter (ug/m^3). EPA set the reference dose (RfD), or the amount below which EPA anticipates no adverse effects from ingesting daily over a lifetime, is 0.0005 milligrams per kilogram bodyweight per day (mg/kg/day)
While several peer review panels recommended that EPA rely on a 2003 study, led by Paula D. Johnson, as its principal study showing cardiac birth defects from TCE exposure, industry says the science is too uncertain to be used for regulatory purposes.
The issue is already prompting controversy at a contaminated site in California, where EPA Region IX, officials have proposed a first-time regulatory limit to prevent cardiac birth defects and other harms due to acute inhalation exposures of TCE.
Officials in agency headquarters are reviewing the proposal from Region IX for an interim Removal Action Level (RAL) for addressing TCE contamination at the Middlefield-Ellis-Whisman (MEW) Superfund site, in Mountain View, CA of 15 ug/m^3, a limit which relies on the IRIS assessment's RfC and other standard cleanup formulae.
But industry groups say the science relative to potential cardiac birth defects is too uncertain to require strict cleanup levels, the method for crafting the limit is at odds with agency policy and the limit is orders of magnitude stricter than similar levels crafted by other agencies (Superfund Report, June 11).
One source familiar with the issue has said that the industry concern may be driven by fears that Region IX's proposed interim RAL, which it crafted to protect construction workers at or near the MEW site, may open the door to strict new cleanup requirements and bolster future personal injury and worker protection claims that might be brought against private and federal responsible parties at the hundreds of sites nationwide where the chemical is present.
But the region's proposal is prompting environmentalists to call on EPA to adopt strict new monitoring requirements in its upcoming guidance for addressing intrusion of toxic vapors from underground sources to guard against exposure from sub surface contamination (Superfund Report, June 25).
In its request to ARA, the site closure group sought advice on several issues that are already in play. It asked ARA to develop additional risk assessment guidance on how to interpret the non-cancer endpoint when it is used for deciding cleanup standards or acceptable levels when closing sites; clarify issues surrounding the potential developmental cardiac malformation for use in understanding clean-up standards and short term exposure levels; and explore the margin of safety measures that EPA used to set the TCE RfC and evaluate if these measures are

consistent with the baseline principles developed for determining the RfC.
The group says that EPA's IRIS assessment "sets a new paradigm for evaluating clean-up standards and risk," and also that EPA's use of the IRIS toxicity values to propose a short-term exposure limit for TCE suggests that the way screening levels are calculated may need to be changed.
The ASC source says that in its effort to create a long-term toxicity number for TCE, EPA did not recognize the short-term implications of that number.
The closure group's proposal questions whether TCE exposures at levels as low as the 2 ug/m^3 can cause cardiac birth defects. Also, it says EPA considered a range of possible values for the RfC and chose one at the low end of the range. Before that choice, EPA's derivation of possible RfC values had involved policy choices that "appear to be new or more conservative" then the usual methods, the request says.
"Is it appropriate to use new science policy without vetting the applicability of the new science policy?" the proposal asks. "The analysis should address if the new process adds an additional margin of safety."
ASC first proposed the idea in June, but the ARA steering committee sent the proposal back to ASC for additional clarification on July 12, sources say.
Although it is unclear exactly what form the review will take, ARA intends to convene an expert panel, which will look at not only at EPA policy but also at how other countries are addressing similar issues. The group would report on its discussions and share its findings with EPA. In addition, EPA officials will be asked to participate. -- Dave Reynolds
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